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PATENT  
Attorney Docket No.: 15270J-004743US  
Client Ref. No.: 209-US-CIP5C3

Fax No. 1-703-872-9306

On

August 16, 2002

TOWNSEND and TOWNSEND and CREW LLP

By:

Rosmarie L. Celli

Rosmarie L. Celli, Reg. No. 42,397

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Dale B. Schenk

Application No.: 09/724,319

Filed: November 27, 2000

For: PREVENTION AND TREATMENT  
OF AMYLOIDOGENIC DISEASE

Examiner: Not Yet Assigned

Art Unit: 1647

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT UNDER 37  
CFR §1.97 and §1.98

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

The references cited on attached PTO/SB/08A and PTO/SB/08B forms are being called to the attention of the Examiner. In accordance with 37 CFR §1.98(d), copies of the references can be found in Application No. 09/322,289, filed May 28, 1999 (Attorney Docket No. 15270J-004740US). It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

Dale B. Schenk  
Application No.: 09/724,319  
Page 2

PATENT

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The Assignee of the instant application is a licensee of U.S. Patent No. 5,688,651, which is directed in part to subject matter related to the instant application. U.S. Patent No. 5,688,651 is now undergoing examination reissue as Application No. 09/441,140. U.S. Application No. 09/441,140 is cited in the PTO/SB/08A form attached hereto. U.S. Patent No. 5,688,651 was cited in the IDS submitted August 20, 2001.

In addition to the commonly owned copending applications directed to related subject matter cited in the IDS submitted on August 20, 2001, Applicant wishes to bring the following applications to the Examiner's attention:

09/979,952 filed 11/26/01 (U.S. National Stage of PCT/US00/15239 filed 06/01/00;

09/979,701 filed 11/26/01 (U.S. National Stage of PCT/US00/14810 filed 05/26/00; and,

09/980,568 filed 03/12/02 (U.S. National Stage of PCT/US00/15302 filed 06/01/00).

In addition to the commonly owned abandoned applications directed to related subject matter cited in the IDS submitted August 20, 2001, Applicant wishes to bring the following application to the Examiner's attention:

60/137,047 filed 06/01/99.

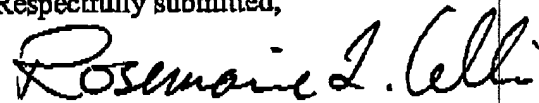
As provided for by 37 CFR 1.97(g) and (h), no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information, and no inference should be made that the information and references cited are, or are considered to be material to patentability because they are in this statement. No inference should be made that the information and references cited are prior art merely because they are in this statement.

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Application No.: 09/724,319  
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Applicant believes that no fee is required for submission of this statement, since it is being submitted prior to the first Office Action. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Rosemarie L. Celli  
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STATEMENT BY APPLICANT**

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**Complete if Known**

Application Number	09/724,319
Filing Date	November 27, 2000
First Named Inventor	Schenk, Dale B.
Group Art Unit	1647
Examiner Name	Turner, Sharon <i>NICHOLS</i>
Attorney Docket Number	15270J-004743US

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant or Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
<i>CS</i>	287	6,294,171	B2	McMichael	09-25-2001	
	234	6,284,221	B1	Schenk, et al.	09-04-2001	
	300	2001/0018053	A1	McMichael	08-30-2001	
	230	6,262,335	B1	Hsiao et al.	07-17-2001	
	231	6,114,133		Seubert et al.	09-05-2000	
<i>CS</i>	221	5,989,566		Cobb et al.	11-23-1999	
<i>CS</i>	284	5,231,170		Averback	07-27-1993	
	242	66/189,604		Chaffin et al.	N/A	
	282	66/189,687		Chen	N/A	
	296	66/184,604		Holtzman et al.	N/A	
	299	60/188,295		Rasmussen et al.	N/A	
	296	66/254,486		Holtzman et al.	N/A	
	297	66/254,486		Holtzman et al.	N/A	
	293	08/441,140		Soleman et al.	N/A	

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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
<i>CS</i>	243	PCT	01/39798	A2		06-07-2001		
	298	PCT	01/42308	A2		06-14-2001		
	801	PCT	01/82284	A2		03-01-2000		
	294	PCT	01/82801	A2		08-30-2001		
<i>CS</i>	240	PCT	00/43039	A1		07-27-2000		
	227	PCT	86/11008	A2		04-27-1995		

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Sheet 2

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Application Number	09/724,319
Filing Date	November 27, 2000
First Named Inventor	Schenk, Dale B.
Group Art Unit	1647
Examiner Name	Turner, Sharon NICHOLS
Attorney Docket Number	15270J-00473US

## OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	228	BARROW, et al., "Solution Conformations and aggregational Properties of Synthetic Amyloid Beta-Peptides of Alzheimer's Disease. Analysis of Circular Dichroism Spectra" <i>J. Mol. Biol.</i> , 225(4): 1075-1093 (1992).	
	239	BEASLEY, "Alzheimer's traced to proteins caused by aging," Reuters, April 20, 2001 7:58 PM ET.	
	285	CAPUTO et al., "Therapeutic approaches targeted at the amyloid proteins in Alzheimer's disease," <i>Glia</i> , Neuropharm., 15:414A-414B (1992).	
	224	<del>Center for Biological Evaluation and Research, U.S. Food and Drug Administration, "Thimerosal in Vaccines (Mercury in Plasma-Derived Products), web site contents found at: <a href="http://www.fda.gov/cber/vaccine/thimerosal.htm">http://www.fda.gov/cber/vaccine/thimerosal.htm</a>, last updated May 16, 2002.</del>	
	266	CHAPMAN, PAUL F., "Model behavior," <i>Nature</i> , 408:915-916 (2000).	
	222	<del>Chemical Abstract database, Abstract of "Injection of Newborn Mice with Seven Chemical Adjuvants to Help Determine Their Safety in Use in Biologics," Chemical Abstract database. (Publication date unknown.)</del>	
	302	CHUNG et al., "Uptake, Degradation, and Release of Fibrillar and Soluble Forms of Alzheimer's Amyloid $\beta$ -Peptide by Microglial Cells," <i>J. Biol. Chem.</i> , 274(45):32301-32308 (1999).	
	291	COLOMA et al., "Transport Across the Primate Blood-Brain Barrier of a Genetically Engineered Chimeric Monoclonal Antibody to the Human Insulin Receptor," <i>Pharm. Res.</i> , 17:268-274 (2000).	
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**Complete if Known**

Application Number	09/724,319
Filing Date	November 27, 2000
First Named Inventor	Schenk, Dale B.
Group Art Unit	1647
Examiner Name	Turner, Sharon <b>NICHOLS</b>
Attorney Docket Number	15270J-004743US

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	228	Elsin, "Elsin and Wyeth Provide Update on Status of Alzheimer's Collaboration," Press Release (3/1/2002).	
	289	ESIRI, "Is an effective immune intervention for Alzheimer's disease in prospect?," <i>Trends in Pharm. Sci.</i> , 22:2-3 (2001).	
	246	FRENKEL et al., "Generation of auto-antibodies towards Alzheimer's disease vaccination," <i>Vaccine</i> , 19:2815-2819 (2001).	
	247	FRENKEL et al., "Immunization against Alzheimer's $\beta$ -amyloid plaques via EFRH phage administration," <i>PNAS USA</i> , 97:11455-11459 (2000).	
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	249	FRIEDLAND, et al., "Neuroimaging of Vessel Amyloid in Alzheimer's Disease," In <i>Cerebrovascular Pathology in Alzheimer's Disease</i> , eds. de la Torre and Hachinski, New York Academy of Sciences, New York, New York (1997).	
	251	GARDAELLA et al., "Intact Alzheimer amyloid precursor protein (APP) is present in platelet membranes and is encoded by platelet mRNA," <i>Biochem. Biophys. Res. Commu.</i> , 173:1292-1295 (1990).	
	252	GEDDES, "N-terminus truncated $\beta$ -amyloid peptides and C-terminus truncated secreted forms of amyloid precursor protein: distinct roles in the pathogenesis of Alzheimer's disease," <i>Neurobiology of Aging</i> , 20:75-79 (1999).	
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	237	GORTNER, <i>Outlines of Biochemistry</i> , pp. 322-323. John Wiley & Sons, Inc., New York (1949).	
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	241	HAASS et al., "Amyloid beta-peptide is produced by cultured cells during normal metabolism," <i>Nature</i> , 358(6303):322-5 (1992).	

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## **Complete If Known**

Application Number	09/724,319
Filing Date	November 27, 2000
First Named Inventor	Schenk, Dale B.
Group Art Unit	1647
Examiner Name	Turner, Sharon NICHOLS
Attorney Docket Number	15270J-004743US

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Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	255	HARIGAYA, et al., "Modified amyloid $\beta$ protein ending at 42 or 40 with different solubility accumulates in the brain of Alzheimer's disease," <i>Biochem. Biophys. Res. Comm.</i> , 211:1015-1022 (1995).	
	229	HAZAMA, et al., "Intranasal Immunization Against Herpes Simplex Virus Infection by Using a Recombinant Glycoprotein D Fused With Immunomodulating Proteins, the B Subunit of Escherichia Coli Heat-Labile Enterotoxin and Interleukin-2," <i>Immunology</i> , Vol. 78: 643-649 (1993).	
	238	HILBICH et al., "Human and rodent sequence analogs of Alzheimer's amyloid $\beta$ A4 share similar properties and can be solubilized in buffers of pH 7.4," <i>Eur. J. Biochem.</i> , 201:81-89 (1991).	
	258	IKEDA, et al., "Immunogold labeling of cerebrovascular and neuritic plaque amyloid fibrils in Alzheimer's disease with an anti- $\beta$ protein monoclonal antibody," <i>Lab. Invest.</i> , 57:446-449 (1987).	
	257	JEN, et al., "Preparation and purification of antisera against different regions or isoforms of b-amyloid precursor protein," <i>Brain Research Protocols</i> , 2:23-30 (1997).	
	256	KIDA, et al., "Early amyloid- $\beta$ deposits show different immunoreactivity to the amino- and carboxy-terminal regions of b-peptide in Alzheimer's disease and Down's syndrome brain," <i>Neuroscience Letters</i> , 193:105-108 (1995).	
	259	LANSBURY, PETER T., "Inhibition of amyloid formation: a strategy to delay the onset of Alzheimer's disease," <i>Curr. Ops. in Chemical Biology</i> , 1:280-287 (1997).	
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	281	MAK, et al., "Polyclonals to b-amyloid (1-42) identify most plaque and vascular deposits in Alzheimer cortex, but not striatum," <i>Brain Research</i> , 667:133-142 (1994).	
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	282	MANN, et al., "The extent of amyloid deposition in brain in patients with Down's syndrome does not depend upon the apolipoprotein E genotype," <i>Neuroscience Letters</i> , 196:105-108 (1995).	
	284	McGeer, et al., "Immunohistochemical localization of beta-amyloid precursor protein sequences in Alzheimer and normal brain tissue by light and electron microscopy," <i>J. of Neuroscience Res.</i> , 31:428-442 (1992).	
	238	MCNEAL et al., "Stimulation of local immunity and protection in mice by intramuscular immunization with triple- or double-layered rotavirus particles and QS-21," <i>Virology</i> , 243:158-168 (1998).	
	265	Mena, et al., "Monitoring pathological assembly of tau and $\beta$ -amyloid proteins in Alzheimer's disease," <i>Acta Neuropathol.</i> , 89:50-56 (1995).	
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Examiner Signature	Date Considered
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	250	NAKAMURA et al., "Histopathological studies on senile plaques and cerebral amyloid angiopathy in aged cynomolgus monkeys," <i>Exp. Anim.</i> , 43:711-718 (1995).	
	268	NAKAMURA, et al., "Carboxyl end-specific monoclonal antibodies to amyloid $\beta$ protein (A $\beta$ ) subtypes (A $\beta$ 40 and A $\beta$ 42(43)) differentiate Ab in senile plaques and amyloid angiopathy in brains of aged cynomolgus monkeys," <i>Neuroscience Letters</i> , 201:151-154 (1995).	
	281	NAKAYAMA et al., "Histopathological studies of senile plaques and cerebral amyloidosis in cynomolgus monkeys," <i>J. of Med. Primatology</i> , 27:244-252 (1998).	
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	280	PARDRIDGE et al., "Chimeric peptides as a vehicle for peptide pharmaceutical delivery through the blood-brain barrier," <i>Biochem. Biophys. Res. Comm.</i> , 148:307-313 (1987).	
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	289	PHILIPPE, et al., "Generation of a monoclonal antibody to the carboxy-terminal domain of tau by immunization with the amino-terminal domain of the amyloid precursor protein," <i>J. of Neuroscience Res.</i> , 46:709-719 (1996).	
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	277	SASAKI et al., "Human choroid plexus is an uniquely involved area of the brain in amyloidosis: a histochemical, immunohistochemical and ultrastructural study," <i>Brain Res.</i> , 755:193-201 (1997).	
	270	SCHENK, et al., " $\beta$ -peptide immunization," <i>Arch. Neurol.</i> , 57:934-938 (2000).	
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	272	SZENDREI, et al., "The effects of aspartic acid-bond isomerization on <i>in vitro</i> properties of the amyloid $\beta$ -peptide as modeled with N-terminal decapeptide fragments," <i>Int. J. Peptide Protein Res.</i> , 47:289-296 (1996).	
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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 6

of

6

## **Complete if Known**

Application Number	09/724,319
Filing Date	November 27, 2000
First Named Inventor	Schenk, Dale B.
Group Art Unit	1847
Examiner Name	Turner, Sharon NICHOLS
Attorney Docket Number	15270J-004743US

## **OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	
	274	WEINER et al., "Nasal administration of amyloid- $\beta$ peptide decreases cerebral amyloid burden in a mouse model of Alzheimer's disease," <i>Annals of Neurology</i> , 48:567-578 (2000).	
	223	<del>Wisconsin Alumni Research Foundation, "Injection of Newborn Mice with Seven Chemical Adjuvants to Help Determine Their Safety in Use in Biologics", U.S. Govt. Res. Develop. Rep., 70(24), 66. (Publication date unknown.)</del>	
	275	WU, et al., "Drug targeting of a peptide radiopharmaceutical through the primate blood-brain barrier in vivo with a monoclonal antibody to the human insulin receptor," <i>J. Clin. Invest.</i> , 100:1804-1812 (1997).	
	282	YAMAGUCHI et al., "Diffuse plaques associated with astroglial amyloid $\beta$ protein, possibly showing a disappearing stage of senile plaques," <i>Acta Neuropathol.</i> , 95:217-222 (1998).	
	280	YOUNKIN, "Amyloid $\beta$ vaccination: reduced plaques and improved cognition," <i>Nature Medicine</i> , 7:18-19 (2001).	

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